DOCUMENT-IDENTIFIER: US 5902238 A
TITLE: Medical tube and apparatus for locating the same in the body of a patient

BSPR:
In a further embodiment, the medical tube is a feeding tube comprising a tube and a permanent magnet associated therewith, wherein the permanent magnet is affixed to the end of a **guide wire** which is removably located within an interior volume of the tube.

BSPR:
In yet a further embodiment, a **guide wire** is disclosed comprising a wire sized to permit a tube to pass thereover and a permanent magnet associated with the end of the wire. In a preferred embodiment, the end of the **guide wire** comprises a spring, and the magnet is positioned within or affixed to the spring.

DRPR:
FIG. 11 illustrates a feeding tube comprising a tube and a magnet associated therewith, wherein the magnet is affixed to the end of a **guide wire** which is removably located within an interior volume of the tube.

DRPR:
FIG. 12 illustrates a **guide wire** having a spring located at the distal end thereof, and wherein a magnet is located within the spring (FIG. 12A) or affixed to either end of the spring (FIGS. 12B and 12C).

DEPR:
The magnet, and hence the medical tube, is detected using a detection apparatus which contains at least two static magnetic field strength sensors configured geometrically to null detection of ambient, homogeneous magnetic fields (e.g., the earth's field), while still detecting the magnetic field

strength gradient produced by the magnet. The detection apparatus is an active, electronic instrument, and can detect the relatively small magnetic field strength gradient produced by the magnet at distances ranging from several centimeters to several decimeters, and preferably from about 2 centimeters to about 3 decimeters. It also indicates the value of the gradient, thus allowing the user to accurately determine the location of the magnet, and hence the medical tube. In a preferred embodiment, the detection apparatus indicates the value of the gradient as both a magnitude and a polarity. By manipulating the magnet until the indicated polarity changes, detection of the location of the medical tube can be verified. Such manipulation of the magnet can be accomplished either by means of an attached **guide wire**, or by rotating the medical tube itself.

DEPR:
This form of magnetization provides the greatest field strength at a given distance for such a cylindrical magnet. In addition, this magnet configuration allows the user to verify that the detection apparatus is sensing the magnet. Specifically, the user can rotate the magnet by, for example, manually rotating the medical tube. Such rotation about the longitudinal axis causes the sensed polarity to change. This change is indicated by the detection apparatus to the user. Alternatively, rather than rotating the medical tube, the magnet may be rotatably fixed to the medical tube such that the user may rotate the magnet by, for example, rotating a **guide wire** running down the medical tube and attached to the magnet.

DEPR:
This aspect of the invention is illustrated in FIGS. 8 and 9. Referring to FIG. 8, medical tube (100) has magnet (102) permanently affixed

to the distal
end (104) of the medical tube. Magnet (102) is magnetized
parallel to the
transverse axis of the tube, such that its dipole, as represented
by arrow
(103), is parallel to the transverse axis of the medical tube.
Referring to
FIG. 9, medical tube (100) has a magnet (102) attached to **guide wire** (107). By
rotation of the **guide wire** as indicated by arrow (106), the
magnet (which is
magnetized such that its dipole, represented by arrow (103), is
parallel to the
transverse axis) is rotated around the longitudinal axis of the
tube, thus
rotating the dipole as indicated by arrow (105).

DEPR:
Similarly, for several procedures in gastroenterology and other
specialties, it
is necessary to pass a **guide wire** into an organ. Once the **guide wire** is in
place (usually with the assistance of an endoscope), another tube
is passed
over the **guide wire**. An example is esophageal stricture
management. In this
instance, there is a narrowing of the esophagus, and patients
complain of
trouble swallowing (dysphagia). A common technique used to
dilate the
stricture is to place a wire through the stricture and into the
stomach, and
then pass progressively larger dilators over the wire. The wire
thus acts like
a monorail or guide to keep the tip of the larger dilator
catheter in the
lumen. This reduces the chance of causing a perforation or hole
in the
esophagus. To ensure that the tip of the **guide wire** is in the
stomach, x-ray
verification is normally utilized.

DEPR:
In the practice of this invention, the location of such a **guide wire** may be
confirmed by placing a magnet at or near the end of the **guide wire**. With
regard to such esophageal stricture guide wires, the wire must be
relatively
stiff. Thus, as illustrated in FIG. 12, a spring (142) is

normally located on the distal end of the wire (140) in order to avoid perforating the esophagus, and the spring is sized such that it can pass down the channel of an endoscope (typically 2.5 to 3.5 mm in diameter). Thus, a small magnet (131) may be located either above (FIG. 12C), below (FIG. 12B) or within (FIG. 12A) the spring of such guide wires. The **guide wire** and spring may then be inserted into the patient by passage down the channel of the endoscope. The present invention permits a physician to confirm that the tip of the **guide wire** remains in the stomach after the use of each progressively larger dilator.

DEPR:
This invention also permits the use of a **guide wire** having a spring tip/magnet end without the need for endoscope placement. Rather, the **guide wire** may be passed directly into the stomach, and its location determined by the apparatus of this invention. The size limitations associated with the use of an endoscope (i.e., the 2.5-3.5 mm diameter channel) can thus be avoided, and larger guide wires or tubes having magnets located near the end can be employed. For example, a flexible tube of about 8 mm in diameter having a magnet located at the end can readily be passed into the stomach, and larger dilators passed over the flexible tube. In this embodiment, the need for a spring is obviated due to the use of the larger diameter flexible tube rather than the **guide wire**.

DEPR:
Since the value of the differential signal indicates the direction of the magnet, the dipole of the magnet is associated with the medical tube in a fixed and known orientation. The medical tubes of this invention have the magnet affixed thereto as represented in FIG. 13A--that is, with the magnet's dipole

pointing parallel to the longitudinal axis of the medical tube in the direction of the proximal end. By maintaining this orientation, the detection apparatus can indicate the orientation of the magnet. This feature of the present invention is useful in a variety of settings. For example, when placed at the end of a feeding tube, the apparatus indicates to the user whether the distal end of the feeding tube is pointing towards the patient's feet, or towards the patient's head. If pointing towards the patient's head, this could indicate that the tube is improperly inserted. Similarly, in the case of guide wires, the user can determine in which direction the **guide wire** is traveling to confirm that it has, for example, entered the desired artery and is traveling in the desired direction.

URPN:
5431640

(102) APP
Claims Rej. 1-3, 5-9, 11-12
23-26,
103 Dep4? plural + 10 plural + 27

Method
13-22
31-40
13, 15, 31, 33

DOCUMENT-IDENTIFIER: US 5622169 A
TITLE: Apparatus and method for locating a medical tube in the body of a patient

30?

DEPR:
The magnet, and hence the medical tube, is detected using a detection apparatus which contains at least two static magnetic field strength sensors configured geometrically to null detection of ambient, homogeneous magnetic fields (e.g., the earth's field), while still detecting the magnetic field strength gradient produced by the magnet. The detection apparatus is an active, electronic instrument, and can detect the relatively small magnetic field strength gradient produced by the magnet at distances ranging from several centimeters to several decimeters, and preferably from about 2 centimeters to about 3 decimeters. It also indicates the value of the gradient, thus allowing the user to accurately determine the location of the magnet, and hence the medical tube. In a preferred embodiment, the detection apparatus indicates the value of the gradient as both a magnitude and a polarity. By manipulating the magnet until the indicated polarity changes, detection of the location of the medical tube can be verified. Such manipulation of the magnet can be accomplished either by means of an attached **guide wire,** or by rotating the medical tube itself.

DEPR:
In a further embodiment, an optional polarity circuit (70) receives the differential signal (41) and provides a polarity signal (71) which is a function of the polarity of the differential signal (41). In a preferred embodiment, the differential signal (41) is a vector, and the polarity of the differential signal is the direction of the vector. A polarity

display driver
(72) then receives the polarity signal (71) and provides a polarity display
signal (73) to a polarity display (74). In this embodiment, the magnet is
preferably made of neodymium iron boron (NdFeB), and is a small cylinder with
dimensions on the order of 0.10 inches in diameter and 0.25 to 0.5 inches in
length. The magnet is magnetized parallel to the diameter or transverse
axis-that is, the north and south magnetic poles are half cylinders. This form
of magnetization provides the greatest field strength at a given distance for
such a cylindrical magnet. In addition, this magnet configuration allows the
user to verify that the detection apparatus is sensing the magnet.
Specifically, the user can rotate the magnet by, for example, manually rotating
the medical tube. Such rotation about the longitudinal axis causes the sensed
polarity to change. This change is indicated by the detection apparatus to the
user. Alternatively, rather than rotating the medical tube, the magnet may be
rotatably fixed to the medical tube such that the user may rotate the magnet
by, for example, rotating a **guide wire** running down the medical tube and
attached to the magnet.

DEPR:
Similarly, for several procedures in gastroenterology and other specialties, it
is necessary to pass a **guide wire** into an organ. Once the **guide wire** is in
place (usually with the assistance of an endoscope), another tube is passed
over the **guide wire**. An example is esophageal stricture management. In this
instance, there is a narrowing of the esophagus, and patients complain of
trouble swallowing (dysphagia). A common technique used to dilate the
stricture is to place a wire through the stricture and into the stomach, and
then pass progressively larger dilators over the wire. The wire thus acts like

a monorail or guide to keep the tip of the larger dilator catheter in the lumen. This reduces the chance of causing a perforation or hole in the esophagus. To ensure that the tip of the **guide wire** is in the stomach, x-ray verification is normally utilized.

DEPR:
In the practice of this invention, the location of such a **guide wire** may be confirmed by placing a magnet at or near the end of the **guide wire**. With regard to such esophageal stricture guide wires, the wire must be relatively stiff. Thus, a spring is normally located on the end of the wire in order to avoid perforating the esophagus, and the spring is sized such that it can pass down the channel of an endoscope (typically 2.5 to 3.5 mm in diameter). Thus, a small magnet may be located either above, below or within the spring of such guide wires. The **guide wire** and spring may then be inserted into the patient by passage down the channel of the endoscope. The present invention permits a physician to confirm that the tip of the **guide wire** remains in the stomach after the use of each progressively larger dilator.

DEPR:
This invention also permits the use of a **guide wire** having a spring tip/magnet end without the need for endoscope placement. Rather, the **guide wire** may be passed directly into stomach, and its location determined by the apparatus of this invention. The size limitations associated with the use of an endoscope (i.e., the 2.5-3.5 mm diameter channel) can thus be avoided, and larger guide wires or tubes having magnets located near the end can be employed. For example, a flexible tube of about 8 mm in diameter having a magnet located at the end can readily be passed into the stomach, and larger dilators passed over the flexible tube. In this embodiment, the need for a spring is obviated due

to the use of the larger diameter flexible tube rather than the **guide wire**.